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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/027,671	02/23/98	SMITH A	4292-0048-55

022850 HM12/0816
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EXAMINER	
TUNG, M	
ART UNIT	**PAPER NUMBER**
1644	14

DATE MAILED: 08/16/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/027,671	AK Smith, et al.
Examiner	**Group Art Unit**
Mary B. Tung	1644

☒ Responsive to communication(s) filed on *May 30, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-45* is/are pending in the applicat

Of the above, claim(s) *15-32* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-14 and 33-45* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-45* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, claims 1-14 and 33-45 in the paper filed 5/30/00, Paper No. 13 is acknowledged. The traversal is on the ground(s) that the Examiner would not be seriously burden by examination of all three groups would involve a search of only nine or more subclasses. This is not found persuasive because the inventions I and II are related as process of making and product made and the inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product, can be made or obtained by protein purification using an affinity matrix. Also, Groups I and III are unique methods. They differ with respect to ingredients and method steps. A Method of cell culture and a method of treatment represent patentably distinct subject matter. They utilize different reagents, are performed using different steps and produce different outcomes. Further, Groups II and III are related as product and process of use and the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the cell composition can be used to produce growth factors *in vitro*, for example. Therefore, a search of the patent and non-patent literature of Group I would not necessarily reveal art relevant to the other Groups. Therefore the inventions are patentably distinct.

2. Groups II and III claims 15-32 are withdrawn from further consideration by the Examiner, 37 C.F.R. 1.142(b), as being drawn to non-elected inventions.

3. Applicant has further elected in Paper No. 13, the species of hematopoietic cells. Claims 1-14 and 33-45 are readable on the elected species.

4. The requirement is still deemed proper and is therefore made FINAL.

Specification

5. The use of the trademarks such as "SOLUMEDROL," page 13, line 18 and page 14, line 7, and so on, of the specification has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

6. Each letter of the trademarks must be capitalized. *See MPEP 608.01(V)* and *Appendix 1.*

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of *35 U.S.C. § 102* that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the Applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the Applicant for patent.

7. Claims 1-6, 9-14, 33-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Kraus (US Patent 5,674,750).

8. The '750 patent teaches a method for obtaining lineage committed hematopoietic stem cells by replacement of culture medium with enhanced proliferative potential, (proliferative and replicative potential, as reacted in claim 12 is known in the art as equivalent to clonogenic expansion, see col. 1 and col. 2, lines 58 and bridging over to col. 3, line 18), wherein the cells are cultured for at least 2 days, as recited in claim 10 (more than 5 days, see col. 12), wherein the medium contains at least one growth factor which stimulates the proliferation of the cells, as recited in claim 11 (see col. 8, lines 31-36), having enhanced biological function, as recited in claims 13, 14 38, 39 (the definition of biological function includes the ability to proliferate to development and regeneration of tissue similar to naturally occurring structure and function on page 11 of the specification, see col. 9), and wherein the lineage committed cells comprise myeloid precursors, as recited in claims 3 and 35 (see col. 2, line 66 and 67), as recited in claims 3, 35 and 43. The '750 patent also teaches lymphoid precursors (see col. 2, line 67), which would inherently comprise T cells or dendritic cells, as recited in claims 5, 6, 36, 37, 44 and 45 (see also col. 3, lines 55 and 56, wherein the cell surface markers include T cell and dendritic cell markers, such as CD19, CD33, CD38 and HLA-Dr, as evidenced by Ager, et al. *(Immunology Today 2nd ed. The Immune Receptor Supplement 1997, 2nd Ed. Elsevier Trends Journals, Cambridge, UK))*. The recitation of claims 40 and 41 wherein the lineage committed cells comprises the increased release of cytokines and increased cytolytic activity would be inherent in the proliferation of myeloid and CD19+, CD33+ and CD38+ cell population taught by the '750 patent, because an increased proliferation inherently induces an increase in cytokines and the CD19+, CD33+ and CD38+ would inherently contain cytotoxic T cell precursors. The '750 patent also teaches that the cells are human, as recited in

claim 1 (see Figure 5). The cells of the '750 patent are inherently cultured, as recited in claim 6. Therefore, the reference teachings anticipate the claimed invention.

Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior art, it has the authority to require the Applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

Claim Rejections - 35 U.S.C. § 103

9. The following is a quotation of *35 U.S.C. § 103* which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraus (US Patent 5,674,750) in view of Schwartz, et al. (US Patent No. 5,728,581).

11. The '750 patent has been discussed as applied to claim 1, *supra*. The claimed invention differs from the reference teaching only by the recitation of the replacement of 50% replacement per day. The '581 patent also teaches the expansion of hematopoietic stem cells. However, in order to allow expansion of the stem cells, the '581 patent teaches that the cell density is kept at an optimum (see col. 9, lines 1-11) and that the medium is exchanged at a rate of ½ per day (see col. 8, lines 59-61) and that the cell numbers are 10,000 (1×10^4) to 200,000 (2×10^5) cells/ml (see col. 6, lines 28-44), which is well within the range cited in claim 8. One of ordinary skill in the art at the time the invention was made would have been motivated to keep the cell density at an optimum and to change ½ of the medium per day, as taught by the '581 patent in the method taught by the '750 patent, in order to allow the expansion of the stem cells. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kraus, et al. (US Patent No. 5,925,567) teach a continuous clonogenic expansion method for hematopoieitc stem cells.

No claim is allowed.

Conclusion

13. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.

14. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The Examiner can normally be reached Monday through Friday from 8:30 am to 5:30 pm. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

August 14, 2000
Mary B. Tung, Ph.D.
Patent Examiner
Group 1640